

PMA Monthly approvals from 7/1/2016 to 7/31/2016

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150006	07/20/2016	PMAO - PMA Orig	CELT ACD VASCULAR CLOSURE DEVICE	VASORUM LTD	Approval for the Celt ACD Vascular Closure Device. This device is indicated for the percutaneous closure of common femoral artery puncture sites while reducing time-to-hemostasis in patients who have undergone diagnostic or interventional intra-arterial catheterization procedures where either 5F or 6F introducer sheaths have been used.
P150017	07/01/2016	PMAO - PMA Orig	CARTIVA SYNTHETIC CARTILAGE IMPLANT	CARTIVA, INC	Approval for use in the treatment of patients with painful degenerative or post-traumatic arthritis (hallux limitus or hallux rigidus) in the first metatarsophalangeal joint with or without the presence of mild hallux valgus.
P150023	07/05/2016	PMAO - PMA Orig	ABSORB GT1 BIORESORBABLE VASCULAR SCAFFOLD (BVS) SYSTEM	ABBOTT VASCULAR INC.	Approval for the ABSORB GT1 BIORESORBABLE VASCULAR SCAFFOLD (BVS) System. This device is indicated for improving coronary luminal diameter in patients with ischemic heart disease due to de novo native coronary artery lesions ≥ 2.5 mm to ≤ 3.75 mm in diameter in lesions ≤ 24 mm in length.
P150037	07/29/2016	PMAO - PMA Orig	CYPASS MICRO-STENT	ALCON RESEARCH, LTD	Approval for the CyPass® System, Model 241-S. This device is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma (POAG).
P150038	07/11/2016	PMAO - PMA Orig	EXABLATE	INSIGHTEC	Approval for the ExAblate Model 4000 Type 1.0 System (ExAblate Neuro). This device is indicated for use in the unilateral Thalamotomy treatment of idiopathic Essential Tremor patients with medication-refractory tremor. Patients must be at least age 22. The designated area in the brain responsible for the movement disorder symptoms (ventralis intermedius) must be identified and accessible for targeted thermal ablation by the ExAblate device.
P160004	07/27/2016	PMAO - PMA Orig	GORE TIGRIS VASCULAR STENT	W. L. GORE & ASSOCIATES, INC.	Approval for the GORE TIGRIS Vascular Stent. This device is intended to improve luminal diameter in patients with symptomatic de-novo or restenotic lesions or occlusions in the native superficial femoral artery (SFA) and proximal popliteal artery (PPA) with reference vessel diameters ranging from 4.0-6.5 mm and lesion lengths up to 240 mm.

Total: 6

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S187	07/08/2016	R - Real-Time Proc	PACEMAKER DEVICES. ADVANTION, INGENIO, VITALIO, FORMIO, ESSENTIO, ACCOLADE, PROPONENT, (INSIGNIA AND ALTRUA 2 SUPPORTED BY LATITUDE CONSULT ONLY)	BOSTON SCIENTIFIC CORP.	Approval for LATITUDE NXT Patient Management System, Release 4.1.1.
P860004/S243	07/22/2016	N - Normal 180 Day	SYNCHROMED II IMPLANTABLE INFUSION PUMP	MEDTRONIC INC.	Approval for a software change to the Model 8870 Application Software Card to reduce the fixed, default Tubing Volume displayed on the priming bolus screen from 0.199 mL to 0.140 mL. This software card is used in the Model 8840 Clinician Programmer to program the Model 8637 SynchroMed II infusion pump. This change is applicable to the full system priming bolus function of the Model 8840 Clinician Programmer to program the Model 8637 SynchroMed II infusion pump. Labeling changes are also being made in the Instructions for Prescribers, Implant Manual and Clinician Programmer Guide to reflect the software change
P870076/S017	07/20/2016	N - Normal 180 Day	FALOPE-RING BAND CONTRACEPTIVE TUBAL OCCLUSION SYSTEM	GYRUS ACMI, INC.	Approval to recover and repackage intact and unused Disposable Falope-Ring® Band Applicators, subject them to a second sterilization process, and make them available for sale and distribution.
P880086/S273	07/25/2016	R - Real-Time Proc	ASSURITY, ASSURITY+, ENDURITY, ACCENT FAMILY OF PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for software modifications to the Merlin.net MN6000 HF Web Application v9.0 software.
P890003/S357	07/08/2016	R - Real-Time Proc	MYCARELINK PATIENT MONITOR SYSTEM	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for software updates to the CareLink Network DDMA Model 2491.
P890017/S017	07/18/2016	Y - 135 Review Tra	CORDIS PALMAZ BALLOON-EXPANDABLE STENT	CORDIS CORP.	Approval for a change of the type of dosimeter used during routine sterilization dose auditing.
P910001/S087	07/07/2016	S - Special CBE	SPECTRANECTICS CVX-300 EXCIMER LASER SYSTEM	SPECTRANETICS CORP.	Approval for the Laser Certification Label modification to conform with CDRH recommendations per Laser Notice 50.
P910023/S372	07/25/2016	R - Real-Time Proc	CURRENT, CURRENT ACCEL, CURRENT+, ELLIPSE, FORTIFY, FORTIFY ASSURA, EPIC/ EPIC+, ATLAS/III+ FAMILY OF ICD'S	St. Jude Medical	Approval for software modifications to the Merlin.net MN6000 HF Web Application v9.0 software.

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P910077/S152	07/08/2016	R - Real-Time Proc	LATITUDE NXT RELEASE 4.1.1	BOSTON SCIENTIFIC	Approval for LATITUDE NXT Patient Management System, Release 4.1.1.
P920047/S092	07/07/2016	R - Real-Time Proc	BLAZER II, BLAZER II HTD TEMPERATURE ABLATION CATHETERS, BLAZER II XP, BLAZER PRIME XP TEMPERATURE ABLATION CATHETERS	BOSTON SCIENTIFIC CORP.	Approval for a design change to the thermistor wire insulating material.
P950037/S165	07/26/2016	R - Real-Time Proc	SOLIA S 45, 53, 60 SIELLO S 45, 53, 60 DRUG-ELUTING PERMANENT RIGHT VENTRICULAR (RV) OR RIGHT ATRIAL (RA) PACEMAKER ELECTRODES	BIOTRONIK, INC.	Approval for the addition of the Siello S and Solia S leads to the ProMRI CRT-D system.
P960040/S370	07/08/2016	R - Real-Time Proc	ICD DEVICES: TELIGEN, ENERGEN, PUNCTUA, INCEPTA, OPRIGEN, INOGEN, DYNAGEN, AUTOGEN.	BOSTON SCIENTIFIC	Approval for LATITUDE NXT Patient Management System, Release 4.1.1.
P960058/S117	07/15/2016	N - Normal 180 Day	HIRESOLUTION BIONIC EAR SYSTEM, HIRES ULTRA COCHLEAR IMPLANT WITH THE HIFOCUS MID-SCALA ELECTRODE	ADVANCED BIONICS	Approval Order should be issued for this PMA supplement.
P960058/S117	07/15/2016	N - Normal 180 Day	HIRESOLUTION BIONIC EAR SYSTEM, HIRES ULTRA COCHLEAR IMPLANT WITH THE HIFOCUS MID-SCALA ELECTRODE	Advanced Bionics LLC	Approval Order should be issued for this PMA supplement.
P970003/S196	07/13/2016	R - Real-Time Proc	VNS THERAPY SYSTEM	CYBERONICS, INC.	Approval for the following device changes: 1) The Model 106 Generator's technical requirement for Heartbeat amplitude detection is being updated to include a minimum lower threshold (i.e. Minimum alower) for each of the generators five (5) gain settings (as well as adjustments to the maximum lower threshold (i.e. alower); 2) The Universal Test System is being updated of the Model 106 Generator so that the updated firmware can be loaded onto Model 106 generators; and 3) Universal Test System (UTS) Updates and Improvements.

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P970003/S197	07/28/2016	N - Normal 180 Day	PULSE, PULSEDUO, DEMIPULSE, DEMIPULSEDUO, ASPIREHC, ASPIRE SR GENERATORS.	CYBERONICS, INC.	Approval for changes to the labeling to update stimulation dosing strategies and modify ECG filter settings.
P970051/S137	07/08/2016	N - Normal 180 Day	NUCLEUS COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval requested for 1) a change in indications to allow MRI of implant recipients at 1.5T with the implant magnet in place for CI512, CI522, CI532, CI422, CI24REH, CI24RE(CA), and CI24RE(ST) provided that a Cochlear-supplied MRI kit is used; 2) a change in indications to allow MRI of implant recipients at 3.0T with the implant magnet removed for CI512, CI522, CI532, CI422, CI24REH, CI24RE(CA), and CI24RE(ST); and 3) consolidation of MRI-related labeling into a single document that provides appropriate instructions for the following Cochlear-manufactured implants: CI512, CI522, CI532, CI422, CI24REH, CI24RE(CA), CI24RE(ST), CI24R(CA), CI24R(CS), CI24R(ST), CI24M, and CI 11+11+2M.
P980018/S022	07/22/2016	R - Real-Time Proc	HERCEPTEST	DAKO A/S	Approval for the DakoLink software version 4.1 update for the HercepTest.
P980040/S065	07/15/2016	P - Panel Track	TECNIS SYMFONY EXTENDED RANGE OF VISION INTRAOCULAR LENS	ABBOTT MEDICAL OPTICS INC	Approval for the Tecnis Symphony Extended Range of Vision Intraocular Lens. The TECNIS® Symphony Extended Range of Vision IOL, Model ZXR00, is indicated for primary implantation for the visual correction of aphakia, in adult patients with less than 1 diopter of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The Model ZXR00 IOL is intended for capsular bag placement only. The TECNIS® Symphony Toric Extended Range of Vision IOLs, Models ZXT150, ZXT225, ZXT300, and ZXT375, are indicated for primary implantation for the visual correction of aphakia and for reduction of residual refractive astigmatism in adult patients with greater than or equal to 1 diopter of preoperative corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The Model Series ZXT IOLs are intended for capsular bag placement only.
P980049/S113	07/07/2016	N - Normal 180 Day	PLATINIUM VR (MODELS 1210 AND 1240) AND PLATINIUM DR (MODELS 1510 AND 1540) ICDS	SORIN CRM S.A.S.	Approval for Platinum ICDs and CRT-Ds.
P990023/S015	07/26/2016	R - Real-Time Proc	CELLUGEL(R) OPHTHALMIC VISCOSURGICAL DEVICE	ALCON LABORATORIES	Approval for a lower endotoxin specification.

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P010012/S417	07/08/2016	R - Real-Time Proc	CRT-D RESYNCHRONIZATION DEVICES, COGNIS, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN	BOSTON SCIENTIFIC CORP.	Approval for LATITUDE NXT Patient Management System, Release 4.1.1.
P010012/S420	07/13/2016	Y - 135 Review Tra	INGEVITY LEAD	BOSTON SCIENTIFIC CORP.	Approval for the removal of redundant specifications and testing associated with batch release and drug stability testing.
P010019/S050	07/19/2016	N - Normal 180 Day	AIR OPTIX PLUS HYDRAGLYDE; AIR OPTIX PLUS HYDRAGLYDE FOR ASTIGMATISM; AIR OPTIX PLUS HYDRAGLYDE MULTIFOCAL; AIR OPTIX PLUS HYDRAGLYDE MULTIFOCAL TORIC.	ALCON LABORATORI ES, INC.	Approval for the addition of 0.04% (400ppm) polyoxyethylene-poluoxxybutylene copolymer (EO45BO10) to the package saline for lotrafilcon B silicone hydrogel soft contact lenses for extended wear.
P010030/S074	07/18/2016	R - Real-Time Proc	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 4000 "LIFEVEST"	ZOLL MANUFACTUR ING CORPORATIO N	Approval for a larger capacity battery pack and associated modifications to the battery pack connection to the printed circuit assembly (PCA) for the WCD 4000 System. This device is indicated for patients of all ages who are at risk for sudden cardiac arrest and either not candidates for or refuse an implantable defibrillator.
P020025/S088	07/07/2016	R - Real-Time Proc	INTELLATIP MIFI XP TEMPERATURE ABLATION SYSTEM	BOSTON SCIENTIFIC	Approval for a design change to the thermistor wire insulating material.
P020045/S075	07/29/2016	R - Real-Time Proc	FREEZOR CARDIAC CRYOABLATION CATHETER, FREEZOR XTRA SURGICAL CATHETERS, FREEZOR MAX SURGICAL CATHETER	MEDTRONIC CRYOCATH LP	Approval for modification to the display monitor of the Gen V Universal CryoConsole (model 106A3).
P030002/S038	07/27/2016	N - Normal 180 Day	CRYSTALENS ACCOMMODATING INTRAOCULAR LENS & TRULIGN TORIC INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Approval for labeling changes to the patient labeling and directions for use.
P030005/S134	07/08/2016	R - Real-Time Proc	CRT-P RESYNCHRONIZATION DEVICES: INVIVE, INTUA, VISIONIST, VALITUDE	GUIDANT CORP.	Approval for LATITUDE NXT Patient Management System, Release 4.1.1.

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P030011/S044	07/05/2016	R - Real-Time Proc	SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T) SYSTEM	SYNCARDIA SYSTEMS, INC.	Approval for a minor change to the Freedom Driver Printed Circuit Board Assembly (PCBA) and addition of an alternate qualified supplier.
P030017/S245	07/28/2016	N - Normal 180 Day	PRECISION SPECTRA SPINAL CORD STIMULATOR (SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a modification to the Precision Spectra Implantable Pulse Generator (IPG) Header for improved manufacturability.
P030022/S036	07/22/2016	S - Special CBE	REFLECTION CERAMIC ACETABULAR HIP SYSTEM	SMITH & NEPHEW, INC.	Approval for a labeling change for the REFLECTION Ceramic Acetabular Hip System which also includes the R3 Ceramic Acetabular Hip System.
P030035/S147	07/25/2016	R - Real-Time Proc	ANTHEM, ALLURE/RF, ALLURE QUADRA/RF FAMILY OF CRT-P'S	ST. JUDE MEDICAL, INC.	Approval for software modifications to the Merlin.net MN6000 HF Web Application v9.0 software.
P030050/S025	07/22/2016	S - Special CBE	SCULPTRA AND SCULPTRA AESTHETIC	Q-MED AB	Approval for labeling changes related to the risks associated with intravascular injection of soft tissue fillers.
P030054/S304	07/25/2016	R - Real-Time Proc	PROMOTE+/RF/Q, PROMOTE ACCEL, PROMOTE QUADRA, UNIFY, UNIFY ASSURA, UNIFY QUADRA, QUADRA ASSURA, EPIC+/HF/HF+/II HF/II+ HF, ATLAS+HF/II HH/II+ HF FAMILY OF CRT-D'S	St. Jude Medical	Approval for software modifications to the Merlin.net MN6000 HF Web Application v9.0 software.
P040034/S025	07/15/2016	R - Real-Time Proc	DURASEAL DURAL SEALANT SYSTEM	INTEGRA LIFESCIENCE S CORPORATION	Approval for changes to three of the polymer resins used to make the Biodome BIO-SET needless access system that is a component of the PEG (polyethylene glycol) vial.
P040038/S031	07/13/2016	O - Normal 180 Day	XACT CAROTID STENT SYSTEM	ABBOTT VASCULAR INC.	Approval for a manufacturing site located at Sterigenics Costa Rica.

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P050023/S102	07/27/2016	R - Real-Time Proc	IPERIA 7 HF-T (DF-1) IPERIA 7 HF-T (DF4) INVENTRA 7 HF-T (DF-1) INVENTRA 7 HF-T (DF4) DEFIBRILLATOR, AUTOMATIC IMPLANTABLE CARDIOVERTER , WITH CARDIAC RESYN	BIOTRONIK, INC.	Approval for the addition of the Siello S and Solia S leads to the ProMRI CRT-D system.
P050037/S074	07/26/2016	Y - 135 Review Tra	RADIESSE 1.5CC	MERZ NORTH AMERICA, INC	Approval for modifications to the automated process for syringe filling.
P050052/S086	07/26/2016	Y - 135 Review Tra	RADIESSE 0.8CC	MERZ NORTH AMERICA, INC	Approval for modifications to the automated process for syringe filling.
P060018/S004	07/20/2016	O - Normal 180 Day	PRESTIGE® CERVICAL DISC	MEDTRONIC SOFAMOR DANEK, INC.	<p>Approval for 1) A 7-year post-approval study to evaluate the longer term safety and effectiveness of the PRESTIGE Cervical Disc. The study will involve the investigational and control patients from the pivotal investigational device exemption (IDE) study arm, as well as the patients who received the device as part of the continued access study (CAS) arm. Data will be collected at 3 years (36 months), 5 years (60 months), and 7 years (84 months) postoperatively for all patients. At each time point, Medtronic will collect the following data: Neck Disability Index score; radiographic information; and neurological status. In addition, all adverse events, including details of the nature, onset, duration, severity, relationship to the device, and relationship to the operative procedure and outcome reported for these patients will also be collected. Reports will be submitted annually until the completion of the study. The results of this long-term data must be reflected in the labeling (via supplement) when the post-approval study is completed, as well as any other time point deemed necessary by FDA if significant new information from this study becomes available.</p> <p>2) A 5-year enhanced surveillance study of the PRESTIGE Cervical Disc to fully characterize adverse events when the device is used in a broader patient population. Medtronic will collect, analyze, and submit all adverse events and complaints received by the company for the PRESTIGE Cervical Disc, as well as information on the total number of devices shipped. The study will commence at the time of PMA approval and reports will be submitted every six months for the first two years and then annually through the fifth year.</p>
P060027/S079	07/07/2016	N - Normal 180 Day	PLATINIUM CRT-D (MODELS 1711 AND 1741)	SORIN CRM S.A.S.	Approval for Platinum ICDs and CRT-Ds.

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P080003/S003	07/07/2016	N - Normal 180 Day	SELENIA DIMENSIONS FULL FIELD DIGITAL MAMMOGRAPHY SYSTEM	HOLOGIC, INC.	Approval for the 30 projection tomosynthesis feature.
P080006/S095	07/13/2016	R - Real-Time Proc	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Approval for a change to the connector sleeve component.
P080013/S013	07/15/2016	R - Real-Time Proc	DURASEAL EXACT SPINE SEALANT SYSTEM	INTEGRA LIFESCIENCE S CORPORATION	Approval for changes to three of the polymer resins used to make the Biodome BIO-SET needless access system that is a component of the PEG (polyethylene glycol) vial.
P090029/S003	07/07/2016	P - Panel Track	PRESTIGE LP(TM) CERVICAL DISC	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for the Prestige LP Cervical Disc. This device is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following discectomy at one level or two contiguous levels for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to abnormality localized to the level of the disc space and at least one of the following conditions confirmed by imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. The PRESTIGE LP _i Cervical Disc is implanted using an anterior approach. Patients should have failed at least 6 weeks of non-operative treatment or have had the presence of progressive symptoms or signs of nerve root/spinal cord compression in the face of continued non-operative management prior to implantation of the PRESTIGE LP Cervical Disc.
P100010/S056	07/29/2016	R - Real-Time Proc	ARCTIC FRONT CARDIAC CRYOABLATION CATHETER, ARCTIC FRONT ADVANCE CARDIAC CRYOABLATION CATHETER, ARCTIC FRONT ST CARDIAC CRYOABLATION CATHETER, FREEZOR MAX CATHETER	MEDTRONIC CRYOCATH LP	Approval for modification to the display monitor of the Gen V Universal CryoConsole (model 106A3).

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P100020/S017	07/07/2016	P - Panel Track	COBAS HPV TEST, 240 TESTS; COBAS HPV TEST, 960 TESTS	ROCHE MOLECULAR SYSTEMS, INC.	<p>Approval for the cobas® HPV Test. The cobas® HPV Test is a qualitative in vitro test for the detection of Human Papillomavirus in cervical specimens collected by a clinician using an endocervical brush/spatula and placed in the ThinPrep® Pap Test™ PreservCyt® Solution or using a cervical broom and placed in SurePath Preservative Fluid. The test utilizes amplification of target DNA by the Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies types HPV16 and HPV18 while concurrently detecting the rest of the high risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68).</p> <p>The cobas® HPV Test is indicated:</p> <p>1) To screen patients 21 years and older with ASC-US (atypical squamous cells of undetermined significance) cervical cytology test results to determine the need for referral to colposcopy;; 2) To be used in patients 21 years and older with ASC-US cervical cytology results, to detect high-risk HPV genotypes 16 and 18. This information, together with the physicians assessment of screening history, other risk factors, and professional guidelines, may be used to guide patient management. The results of this test are not intended to prevent women from proceeding to colposcopy; 3) In women 30 years and older, the cobas® HPV Test can be used with cervical cytology to adjunctively screen to detect high risk HPV types. This information, together with the physician's assessment of screening history, other risk factors, and professional guidelines, may be used to guide patient management; and 4) In women 30 years and older, the cobas® HPV Test can be used to detect HPV genotypes 16 and 18. This information, together with the physicians assessment of screening history, other risk factors, and professional guidelines, may be used to guide patient management; and 5) In women 25 years and older, the cobas® HPV Test can be used for specimens collected only in ThinPrep® Pap Test™ PreservCyt® Solution as a first-line primary cervical cancer screening test to detect high risk HPV, including genotyping for 16 and 18. Women who test negative for high risk HPV types by the cobas® HPV Test should be followed up in accordance with the physicians assessment of screening and medical history, other risk factors, and professional guidelines. Women who test positive for HPV genotypes 16 and/or 18 by the cobas® HPV Test should be referred to colposcopy. Women who test high risk HPV positive and 16/18 negative by the cobas® HPV Test (12 other HR HPV positive) should be evaluated by cervical cytology to determine the need for referral to colposcopy.</p>
P100026/S043	07/28/2016	R - Real-Time Proc	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval for changes on the design of the Wand, which is used for communication between the Neurostimulator and the Remote Monitor, and the Neurostimulator and the Programmer.
P100034/S015	07/13/2016	N - Normal 180 Day	OPTUNE	NOVOCURE, LTD.	Approval for a smaller, lighter weight version of the original Optune _z System, referred to as the Optune _z System (NovoTTF-200A System).
P100045/S009	07/25/2016	R - Real-Time Proc	CARDIOMEMS HF SYSTEM	St. Jude Medical	Approval for software modifications to the Merlin.net MN6000 HF Web Application v9.0 software.

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P110010/S122	07/15/2016	Y - 135 Review Tra	PROMUS(ELEMENT PLUS/ PREMIER) EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for an alternate filter for solution filtration during two manufacturing processes.
P110013/S059	07/22/2016	O - Normal 180 Day	RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC, INC.	Approval to update the labeling for the Resolute Integrity Zotarolimus-Eluting Coronary Stent System Instructions for Use (IFU) for both the Rapid Exchange (RX) and Over-The-Wire (OTW) delivery systems to include the most current clinical follow-up data for the Global RESOLUTE Clinical Trial Program and the Resolute Integrity US (RI-US) Primary Enrollment Group (PEG) Post-Approval Study.
P110035/S034	07/20/2016	Y - 135 Review Tra	EPIC VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the addition of a sterilization chamber at the Synergy Health Ireland Limited, Tullamore facility.
P110042/S059	07/08/2016	R - Real-Time Proc	SUBCUTANEOUS ICD DEVICES: EMBLEM.	Boston Scientific Corporation	Approval for LATITUDE NXT Patient Management System, Release 4.1.1.
P120005/S047	07/08/2016	R - Real-Time Proc	DEXCOM G4 PLATINUM RECEIVER, G4 PLATINUM PEDIATRIC RECEIVER, DEXCOM G5 MOBILE RECEIVER, DEXCOM G4 PLATINUM RECEIVER WITH SHARE, G4 PLATINUM RECEIVER WITH SHARE PEDIATRIC, G4 PLATINUM PROFESSIONAL RECEIVER	DEXCOM, INC.	Approval for the replacement of the receiver speaker component of the Dexcom G4 PLATINUM/G5 Mobile. Together with the proposed component change, the supplement requested approval of changes to the speaker installation method. The proposed changes occur at Dexcom Inc. as well as OnCore Manufacturing Services, Dexcoms approved supplier. The receiver is a component of the Dexcom G4 Platinum and Dexcom G5 Mobile Continuous Glucose Monitoring Systems.
P120020/S013	07/13/2016	O - Normal 180 Day	SUPERA PERIPHERAL STENT SYSTEM	ABBOTT VASCULAR (IDEF TECHNOLOGIES INC)	Approval for a manufacturing site located at Sterigenics Costa Rica.

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P130004/S002	07/21/2016	O - Normal 180 Day	RESURE SEALANT	OCULAR THERAPEUTICS, INC.	Approval for the ReSure® Sealant Device Exposure Registry post-approval study protocol.
P130007/S014	07/06/2016	R - Real-Time Proc	ANIMAS VIBE SYSTEM	ANIMAS CORP.	Approval for a change to the solder composition for three subassemblies used in the Animas Vibe pump as required for RoHS compliance. The Animas Vibe pump is a component of the Animas Vibe System.
P130016/S012	07/08/2016	N - Normal 180 Day	NUCLEUS HYBRID COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval requested for 1) a change in indications to allow MRI of implant recipients at 1.5T with the implant magnet in place for CI512, CI522, CI532, CI422, CI24REH, CI24RE(CA), and CI24RE(ST) provided that a Cochlear-supplied MRI kit is used; 2) a change in indications to allow MRI of implant recipients at 3.0T with the implant magnet removed for CI512, CI522, CI532, CI422, CI24REH, CI24RE(CA), and CI24RE(ST); and 3) consolidation of MRI-related labeling into a single document that provides appropriate instructions for the following Cochlear-manufactured implants: CI512, CI522, CI532, CI422, CI24REH, CI24RE(CA), CI24RE(ST), CI24R(CA), CI24R(CS), CI24R(ST), CI24M, and CI 11+11+2M.
P130022/S008	07/14/2016	R - Real-Time Proc	SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEURO CORPORATION	Approval for software changes to the Clinician Programmer Model PG2000.
P130028/S009	07/14/2016	R - Real-Time Proc	ALGOVITA SPINAL CORD STIMULATION SYSTEM	NUVECTRA CORPORATION	Approval for software and instructions for use (IFU) changes to the Model 4500 Clinician Programmer.
P140010/S013	07/06/2016	N - Normal 180 Day	IN.PACT ADMIRAL PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Approval for a 150 mm balloon length.
P140020/S002	07/26/2016	R - Real-Time Proc	BRACANALYSIS CDX	MYRIAD GENETIC LABORATORIES	Approval for 1) labeling changes to include results from additional non-clinical studies, and 2) a variant reclassification process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140021/S005	07/25/2016	N - Normal 180 Day	ELECSYS ANTI-HCV II TEST SYSTEM	ROCHE DIAGNOSTICS	Approval for the migration of claims from the FDA approved Elecsys Anti-HCV II Immunoassay and Elecsys PreciControl Anti-HCV on the cobas e 601 immunoassay analyzer to the Modular ANALYTICS E170 analyzer. The device, as modified, will be marketed under the trade name Elecsys Anti-HCV II Immunoassay and Elecsys PreciControl Anti-HCV and is indicated for: Elecsys Anti-HCV II Immunoassay: Immunoassay for the in vitro qualitative detection of antibodies to hepatitis C virus (HCV) in human adult and pediatric (ages 18 months through 21 years) serum and plasma (potassium EDTA, lithium heparin, sodium heparin, and sodium citrate). Assay results, in conjunction with other laboratory results and clinical information, may be used to aid in the presumptive diagnosis of HCV infection in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis C infection. The test does not determine the state of infection or associated disease. The electrochemiluminescence immunoassay ECLIA is intended for use on the cobas e 601 and MODULAR ANALYTICS E170 immunoassay analyzers. Elecsys PreciControl Anti-HCV: Elecsys PreciControl Anti-HCV is used for quality control of the Elecsys Anti-HCV and the Elecsys Anti-HCV II immunoassays on the cobas e 601 and the MODULAR ANALYTICS E170 immunoassay analyzers.
P140026/S002	07/19/2016	O - Normal 180 Day	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Approval of the following changes to the post-approval study for the device: editorial, protocol, exclusion changes, as well as verbage changes.
P150003/S003	07/29/2016	P - Panel Track	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM(OVER-THE-WIRE& MONORAIL)	BOSTON SCIENTIFIC CORP.	Approval for the SYNERGY ₂ Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail ₂ and Over-The-Wire). This device is indicated for improving luminal diameter in patients, including those with diabetes mellitus, with symptomatic heart disease, stable angina, unstable angina, non-ST elevation MI or documented silent ischemia due to atherosclerotic lesions in native coronary arteries ≥ 2.25 mm to ≤ 4.00 mm in diameter in lesions ≤ 34 mm in length.
P150005/S005	07/07/2016	N - Normal 180 Day	INTELLANAV OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for design changes to incorporate a magnetic sensor into the Blazer Open Irrigated Ablation Catheter. The device, as modified, will be marketed under the trade name IntellaNav Open-Irrigated Ablation Catheter and is indicated for: The IntellaNav ₂ Open-Irrigated Catheter, when used with a Maestro 4000® Radiofrequency (RF) Controller and MetriQ ₂ Irrigation Pump, is indicated for:
P150005/S006	07/05/2016	O - Normal 180 Day	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Avaimed S.A. de C.V. Ave. Industrial 20905 Interior A, Ciudad Industrial, C.P. 22444 Tijuana, Baja California, Mexico.
P150012/S004	07/14/2016	R - Real-Time Proc	INGENIO 2 MRI PACEMAKERS.	BOSTON SCIENTIFIC	Approval for design changes to the accelerometer component and associated changes.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150012/S006	07/13/2016	Y - 135 Review Tra	ACUITY X4 LEAD	BOSTONSCIENTIFIC	Approval for the removal of redundant specifications and testing associated with batch release and drug stability testing.
P150019/S007	07/27/2016	R - Real-Time Proc	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Approval to implement a change in the material composition of the loaner pump interior paper foam tray used for packaging the pump.
P150033/S002	07/08/2016	R - Real-Time Proc	MICRA	MEDTRONIC INC.	Approval for software updates to the CareLink Network DDMA Model 2491.
P150033/S003	07/18/2016	R - Real-Time Proc	MEDTRONIC MICRA TRANSCATHETER PACING SYSTEM	MEDTRONIC INC.	Approval for shelf life extension to 12 months.

Total: 73

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N12159/S038	07/01/2016	X - 30-Day Notice	SURGICEL ABSORBABLE HEMOSTAT	ETHICON, INC.	Implementation of new production equipment (automatic foiling equipment).
P830055/S171	07/01/2016	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Introduction of digital, automated hydrometers and water flow rate alarms for products of the LCS® Total Knee System that are processed through the final clean lines.
P830061/S131	07/14/2016	X - 30-Day Notice	ADHESIVE, CAPSURE SENSE LEAD, CAPSURE SP NOVUS LEAD, VITATRON CRYSTALLINE LEAD, VITATRON EXCELLENCE PS+ LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of a peel strength test to the manufacturing process.
P840001/S329	07/01/2016	X - 30-Day Notice	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES, RESUME, SPECIFY, AND VECTRIS SPINAL CORD	MEDTRONIC NEUROMODULATION	Relocate the manufacturing facility for an external supplier of components for neuromodulation leads.
P840001/S330	07/07/2016	X - 30-Day Notice	RESTORE, ITREL AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES, RESUME, SPECIFY, AND VECTRIS SPINAL CORD	MEDTRONIC NEUROMODULATION	Process parameter changes related to package sealing, tray cleaning, and packaging inspection.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S331	07/06/2016	X - 30-Day Notice	MEDTRONIC SPINAL CORD STIMULATION THERAPY	MEDTRONIC NEUROMODULATION	Transfer of molding and assembly of the lead tip used in the Model 3888 Pisces-Quad® Lead, part number 103162001 from Medtronic Energy and Component Center (MECC), to Accumold located in Ankeny, Iowa.
P840001/S332	07/07/2016	X - 30-Day Notice	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES, RESUME, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Addition of new peel test and pouch seal equipment used in the Pouch Sealing process and Blister Package and Pouch Peel Testing process and introduction of a new peel test operation procedure at the Medtronic Sullivan Lake facility.
P840001/S333	07/27/2016	X - 30-Day Notice	RESTORE, LTREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES, RESUME, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Update to the welding process parameters, welding electrode tip geometry, and accompanying documentation used in the manufacture of your Medium Rate battery assemblies for your Restore, Itrel, and Synergy Spinal Cord Stimulation (SCS) Systems; Activa Deep Brain Stimulation (DBS) Therapy System; Activa Dystonia Therapy System; Reclaim DBS Therapy for OCD System; InterStim Therapy System; Enterra Therapy System; and SyncroMed Infusion System.
P840001/S334	07/20/2016	X - 30-Day Notice	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES, RESUME, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Implementation of peel strength testing in the manufacturing lines at Medtronic Puerto Rico Operations Co. Villalba and Medtronic Puerto Rico Operations Juncos.
P840001/S335	07/29/2016	X - 30-Day Notice	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEM AND PISCES, SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEAD	MEDTRONIC NEUROMODULATION	Use of new capacitors and diodes for the manufacture of hybrid assemblies that are used on several Medtronic Neuromodulation implantable neurostimulators (INS).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P850089/S118	07/14/2016	X - 30-Day Notice	CAPSURE SP NOVUS LEAD, CAPSURE SP Z LEAD, CAPSURE Z NOVUS LEAD,	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEME	Implementation of a peel strength test to the manufacturing process.
P860004/S251	07/07/2016	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Process parameter changes related to package sealing, tray cleaning, and packaging inspection.
P860004/S252	07/07/2016	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Component and manufacturing process changes to the Catheter Access Port (CAP) Valve, a subcomponent of the Model 8637 SynchroMed II Drug Infusion Pump (Model 8637 Pump).
P860004/S253	07/07/2016	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Addition of new peel test and pouch seal equipment used in the Pouch Sealing process and Blister Package and Pouch Peel Testing process and introduction of a new peel test operation procedure at the Medtronic Sullivan Lake facility.
P860004/S254	07/27/2016	X - 30-Day Notice	SYNCHROMED(TM) INFUSION SYSTEM	MEDTRONIC INC.	Update to the welding process parameters, welding electrode tip geometry, and accompanying documentation used in the manufacture of your Medium Rate battery assemblies for your Restore, Itrel, and Synergy Spinal Cord Stimulation (SCS) Systems; Activa Deep Brain Stimulation (DBS) Therapy System; Activa Dystonia Therapy System; Reclaim DBS Therapy for OCD System; InterStim Therapy System; Enterra Therapy System; and SynchroMed Infusion System.
P860004/S255	07/20/2016	X - 30-Day Notice	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Implementation of peel strength testing in the manufacturing lines at Medtronic Puerto Rico Operations Co. Villalba and Medtronic Puerto Rico Operations Juncos.
P860004/S256	07/28/2016	X - 30-Day Notice	SYNCHROMED II INFUSION SYSTEM	MEDTRONIC INC.	Add additional monitor to the SynchroMed II propellant backfill plug weld process for hardness and penetration specifications.
P860022/S059	07/25/2016	X - 30-Day Notice	BOSTON EQUALENS, EQUALENS II (ITAFUROFOCON A)& (OPRIFOCON A) RIGID GAS PERMEABLE CONTACT LENS	POLYMER TECHNOLOGY CORP.	Alternate supplier of a critical raw material component.
P860057/S150	07/05/2016	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT MAGNA EASE PERICARDIAL AORTIC BIOPROSTHESIS WITH THERMAFIX TISSUE PROCESS	EDWARDS LIFESCIENCE S, LLC.	Use of an automated method for wireforming.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P860057/S151	07/01/2016	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT	EDWARDS LIFESCIENCE S, LLC.	Use of an automated laser measurement system for in-process dimensional inspections.
P880081/S040	07/29/2016	X - 30-Day Notice	TECNIS CL FOLDABLE SILICONE INTRAOCULAR LENS	ABBOTT MEDICAL OPTICS INC	Change in the Bioburden Test Method used in the manufacturing of the TECNIS CL, Model Z9002, SENSAR Acrylic Intraocular Lenses (IOLs), Models AR40, AAB00, ZCB00, ZCB00V, and ZMB00, and TECNIS Acrylic Monofocal IOL, Model ZA9003.
P890003/S359	07/14/2016	X - 30-Day Notice	CAPSURE VDD 2 LEAD, SERVICE KIT-PACEMAKER REPAIR KIT, VITATRON BRILLIANT S+ VDD LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of a peel strength test to the manufacturing process.
P900061/S140	07/14/2016	X - 30-Day Notice	END CAP, UPSIZING SLEEVE	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of a peel strength test to the manufacturing process.
P910023/S374	07/19/2016	X - 30-Day Notice	CURRENT+ ICDS	St. Jude Medical	Changes to the hybrid solder reflow process.
P910073/S136	07/25/2016	X - 30-Day Notice	ENDOTAK RELIANCE IS-1 AND ENDOTAK RELIANCE 4-SITE LEAD	BOSTON SCIENTIFIC	Change in a reactant used for preparation of the key intermediate in the synthesis of dexamethasone acetate.
P920015/S181	07/14/2016	X - 30-Day Notice	"Y" ADAPTOR/EXTENDER KIT, DF-1 CONNECTOR PORT PIN PLUG KIT, LEAD ADAPTOR, SUBCUTANEOUS LEAD, TRANSVENE CS/SVC LEAD, TUNNELING TOOL	MEDTRONIC INC.	Implementation of a peel strength test to the manufacturing process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P920015/S181	07/14/2016	X - 30-Day Notice	"Y" ADAPTOR/EXTENDER KIT, DF-1 CONNECTOR PORT PIN PLUG KIT, LEAD ADAPTOR, SUBCUTANEOUS LEAD, TRANSVENE CS/SVC LEAD, TUNNELING TOOL	MEDTRONIC INC.	Implementation of a peel strength test to the manufacturing process.
P930039/S153	07/14/2016	X - 30-Day Notice	CAPSUREFIX LEAD, CAPSUREFIX NOVUS LEAD, VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of a peel strength test to the manufacturing process.
P950008/S013	07/18/2016	X - 30-Day Notice	SILIKON 1000	ALCON	Addition of a new biological indicator to be used as an alternate process challenge device (PCD) for terminal sterilization of SILIKON 1000.
P950022/S093	07/19/2016	X - 30-Day Notice	DURATA, OPTISURE	ST. JUDE MEDICAL, INC.	Alternate analytical testing laboratory for the identification testing of dexamethasone sodium phosphate for incoming monolithic controlled release devices.
P950024/S068	07/14/2016	X - 30-Day Notice	CAPSURE EPICARDIAL PACING LEAD	MEDTRONIC INC.	Implementation of a peel strength test to the manufacturing process.
P960009/S252	07/01/2016	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY	MEDTRONIC INC.	Relocate the manufacturing facility for an external supplier of components for neuromodulation leads.
P960009/S253	07/07/2016	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Process parameter changes related to package sealing, tray cleaning, and packaging inspection.
P960009/S254	07/07/2016	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Addition of new peel test and pouch seal equipment used in the Pouch Sealing process and Blister Package and Pouch Peel Testing process and introduction of a new peel test operation procedure at the Medtronic Sullivan Lake facility.
P960009/S255	07/27/2016	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Update to the welding process parameters, welding electrode tip geometry, and accompanying documentation used in the manufacture of your Medium Rate battery assemblies for your Restore, Itrel, and Synergy Spinal Cord Stimulation (SCS) Systems; Activa Deep Brain Stimulation (DBS) Therapy System; Activa Dystonia
P960009/S256	07/20/2016	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Implementation of peel strength testing in the manufacturing lines at Medtronic Puerto Rico Operations Co. Villalba and Medtronic Puerto Rico Operations Juncos.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960009/S257	07/29/2016	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Use of new capacitors and diodes for the manufacture of hybrid assemblies that are used on several Medtronic Neuromodulation implantable neurostimulators (INS).
P960013/S082	07/19/2016	X - 30-Day Notice	TENDRIL SDX, TENDRIL ST, TENDRIL STS, OPTISENSE	PACESETTER, INC.	Alternate analytical testing laboratory for the identification testing of dexamethasone sodium phosphate for incoming monolithic controlled release devices.
P960030/S045	07/19/2016	X - 30-Day Notice	ISOFLEX OPTIM	PACESETTER, INC.	Alternate analytical testing laboratory for the identification testing of dexamethasone sodium phosphate for incoming monolithic controlled release devices.
P960040/S375	07/22/2016	X - 30-Day Notice	DYNAGEN ₂ MODELS: D020, D021, D022, D023; D150, D151, D152, D153; INOGEN ₂ MODELS: D010, D011, D012, D013, D140, D141, D142, D143; ORIGEN ₂ MODELS: D000, D001, D002, D003, D050, D051, D052, D053	BOSTON SCIENTIFIC	Modifications to the battery weld process.
P960043/S093	07/01/2016	X - 30-Day Notice	PROSTAR XL 10F PERCUTANEOUS VASCULAR SURGICAL SYSTEM	ABBOTT VASCULAR INC.	Modification to the pre-sterile Sheath-Guide tensile strength acceptance criteria.
P970003/S201	07/29/2016	X - 30-Day Notice	VNS THERAPY SYSTEM	CYBERONICS, INC.	Removal of the bead blast process from the standard final generator production process and retaining it as an optional process for processing generator cans that do not meet visual acceptance criteria.
P970004/S214	07/01/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM (URINARY)	MEDTRONIC NEUROMODULATION	Relocate the manufacturing facility for an external supplier of components for neuromodulation leads.
P970004/S215	07/07/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Process parameter changes related to package sealing, tray cleaning, and packaging inspection.
P970004/S216	07/07/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Addition of new peel test and pouch seal equipment used in the Pouch Sealing process and Blister Package and Pouch Peel Testing process and introduction of a new peel test operation procedure at the Medtronic Sullivan Lake facility.
P970004/S217	07/13/2016	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Changes to tapering process for tubing used on leads from a manual tapering process to a semi-automated tapering process and replacement of a ring gauge outer diameter measurement system with a laser micrometer.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970004/S219	07/27/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Update to the welding process parameters, welding electrode tip geometry, and accompanying documentation used in the manufacture of your Medium Rate battery assemblies for your Restore, Itrel, and Synergy Spinal Cord Stimulation (SCS) Systems; Activa Deep Brain Stimulation (DBS) Therapy System; Activa Dystonia Therapy System; Reclaim DBS Therapy for OCD System; InterStim Therapy System; Enterra Therapy System; and SyncroMed Infusion System.
P970004/S220	07/20/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Implementation of peel strength testing in the manufacturing lines at Medtronic Puerto Rico Operations Co. Villalba and Medtronic Puerto Rico Operations Juncos.
P970051/S148	07/21/2016	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Addition of automated slot cutting of the sorting ring for implant production.
P980016/S594	07/14/2016	X - 30-Day Notice	EVERA MRI/EVERA S DR/ EVERA S VR/EVERA XT DR/ EVERA XT VR/MAXIMO II/ PROTECTA/PROTECTA VR/ PROTECTA XT/SECURA DR/SECURA/VIRTUOSO II DR/VR/VISIA AF MRI/VISIA AF VR	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of a peel strength test to the manufacturing process.
P980016/S595	07/28/2016	X - 30-Day Notice	EVERA MRI ICD DDMB1D4, DDMC3D4, DVMB1D4, DVMC3D4; VISIA AF MRI VR ICD DVFB1D4, DVFC3D4; VISIA AF VR ICD DVAB1D1, DVAB1D4,	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update to the distribution control sorter tool system.
P980024/S014	07/13/2016	X - 30-Day Notice	PATH VYSION HER-2 DNA PROBE KIT	ABBOTT MOLECULAR, INC.	Removal of testing at the cell pellet stage for 2 components of the PathVysion HER-2 DNA Probe Kit: (1) ProbeChek HER-2/neu Cut-Off Control Slides (List No. 02J04-030), (2) ProbeChek HER-2/neu Normal Control Slides (List No. 02J05-030). The second change involves adding the RM2255 Rotary Microtome to the manufacturing procedures of the ProbeChek HER-2/neu Cut-Off Control Slides, the ProbeChek Her-2/neu Normal Control Slides, and 2 components of the Vysis ALK Break Apart FISH Probe Kit: (1) ProbeChek ALK Negative Control Slides (06N38-005), (2) ProbeChek ALK Postitive Control Slides (06N38-010).
P980035/S465	07/05/2016	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG ADDR01, ADDR03, ADDR06, ADDR11, ADDRS1, SEDR01, SESR01, VEDR01, ADD01, SEDRL1, SED01, SES01, ADSR01,	MEDTRONIC INC.	Implementation of new laser welding equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S466	07/06/2016	X - 30-Day Notice	ADVISA DR IPG, DR MRI IPG, SR MRI IPG	MEDTRONIC INC.	New instrumentation and an updated test method for use in the battery manufacturing process.
P980035/S467	07/20/2016	X - 30-Day Notice	ADVISA DR IPG; DR MRI IPG; SR MRI IPG	MEDTRONIC INC.	Alternate printed wiring board for use in hybrid manufacturing.
P980035/S468	07/14/2016	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG; ADVISA DR IPG; ADVISA DR MRI IPG; ADVISA SR MRI IPG; RELIA IPG	MEDTRONIC INC.	Implementation of a peel strength test to the manufacturing process.
P980040/S071	07/29/2016	X - 30-Day Notice	SENSAR SOFT ACRYLIC INTRAOCULAR LENS	ABBOTT MEDICAL OPTICS INC	Change in the Bioburden Test Method used in the manufacturing of the TECNIS CL, Model Z9002, SENSAR Acrylic Intraocular Lenses (IOLs), Models AR40, AAB00, ZCB00, ZCB00V, and ZMB00, and TECNIS Acrylic Monofocal IOL, Model ZA9003.
P980044/S033	07/25/2016	X - 30-Day Notice	SUPARTZ DEVICE FAMILY, SUPARTZ FX, VISCO-3	SEIKAGAKU CORP.	Update the application software for the existing intrinsic viscosity measuring system used for the manufacture of SUPARTZ FX and VISCO-3.
P980050/S105	07/14/2016	X - 30-Day Notice	TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Implementation of a peel strength test to the manufacturing process.
P990075/S037	07/05/2016	X - 30-Day Notice	MENTOR SALINE-FILLED AND SPECTRUM BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Use of previously approved Semi-Automated Primary Packaging Equipment SPPS following relocation from the Main Assembly Controlled Manufacturing Environment CME room to the Primary Packaging CME Room at the Mentor Irving, Texas facility.
P990080/S043	07/29/2016	X - 30-Day Notice	TECNIS ACRYLIC INTRAOCULAR LENS	ABBOTT MEDICAL OPTICS INC	Change in the Bioburden Test Method used in the manufacturing of the TECNIS CL, Model Z9002, SENSAR Acrylic Intraocular Lenses (IOLs), Models AR40, AAB00, ZCB00, ZCB00V, and ZMB00, and TECNIS Acrylic Monofocal IOL, Model ZA9003.
P000015/S014	07/21/2016	X - 30-Day Notice	NUCLEUS AUDITORY BRAINSTEM IMPLANT	COCHLEAR AMERICAS	Addition of automated slot cutting of the sorting ring for implant production.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000018/S047	07/26/2016	X - 30-Day Notice	BETA-CATH (TM) SYSTEM	BEST VASCULAR, INC	Use of a new supplier and a change to the Bacterial Endotoxin Test sampling plan.
P000025/S088	07/08/2016	X - 30-Day Notice	COMBI 40+ COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Gain additional manufacturing space and flexibility with respect to allocation of work spaces for implant production and process flow within implant manufacturing.
P000037/S046	07/25/2016	X - 30-Day Notice	ON-X PROSTHETIC HEART VALVE AND ON-X ASCENDING	ON-X LIFE TECHNOLOGIES, INC.	Use of an additional Coordinate Measuring Machine for heart valve housing measurements.
P010003/S024	07/07/2016	X - 30-Day Notice	BIOGLUE SURGICAL ADHESIVE	CRYOLIFE, INC.	Change in the sampling plan used for BioGlue Surgical Adhesive testing.
P010012/S425	07/25/2016	X - 30-Day Notice	ACUITY SPIRAL LEAD, ACUITY X4 LEAD	BOSTON SCIENTIFIC CORP.	Change in a reactant used for preparation of the key intermediate in the synthesis of dexamethasone acetate.
P010012/S426	07/22/2016	X - 30-Day Notice	DYNAGEN ₂ MODELS: G150, G151, G154, G156, G158; INOGEN ₂ MODELS: G140, G141, G146, G148; ORIGEN	BOSTON SCIENTIFIC CORP.	Modifications to the battery weld process.
P010015/S301	07/06/2016	X - 30-Day Notice	CONSULTA CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	New instrumentation and an updated test method for use in the battery manufacturing process.
P010015/S302	07/20/2016	X - 30-Day Notice	CONSULTA, SYNCRA, VIVA CRT-P	MEDTRONIC INC.	Alternate printed wiring board for use in hybrid manufacturing.
P010015/S303	07/14/2016	X - 30-Day Notice	ATTAIN BIPOLAR OTW LEAD, ATTAIN OTW LV LEAD, CONSULTA CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Implementation of a peel strength test to the manufacturing process.
P010030/S077	07/07/2016	X - 30-Day Notice	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Addition of automated incoming inspection measuring test equipment.
P010030/S078	07/21/2016	X - 30-Day Notice	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Change to the LifeVest 4000 Monitor burn-in test procedure.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S555	07/14/2016	X - 30-Day Notice	AMPLIA/BRAVA/ CONCERTO/INSYNC SENTRY/INSYNC MAXIMO/ PROTECTA/VIVA IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of a peel strength test to the manufacturing process.
P010031/S556	07/28/2016	X - 30-Day Notice	AMPLIA MRI CRT-D DTMB1D4; AMPLIA MRI QUAD CRT-D DTMB1QQ; COMPIA MRI CRT-D DTMC1D4; COMPIA MRI QUAD CRT-D DTMC1QQ	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update to the distribution control sorter tool system.
P010062/S010	07/25/2016	X - 30-Day Notice	BOSTON ORTHOKERATOLOGY (OPRIFOCON A) SHAPING LENS FOR OVERNIGHT WEAR AND VISION SHAPING TREATMENT	BAUSCH & LOMB	Alternate supplier of a critical raw material component.
P020004/S132	07/07/2016	X - 30-Day Notice	GORE EXCLUDER AAA ENDOPROSTHESIS & ILIAC BRANCH ENDOPROSTHESIS	W.L. GORE & ASSOCIATES, INC	Implementation of a change to the thermal processing of Ultra Thin Wall (UTW) basetube graft components of the Gore Excluder AAA Endoprosthesis and the Gore Excluder Iliac Branch Endoprosthesis.
P020004/S133	07/11/2016	X - 30-Day Notice	GORE EXCLUDER ILIAC BRANCH ENDOPROSTHESIS	W.L. GORE & ASSOCIATES, INC	Implementation of circumferential tensile testing as a lot acceptance test for the graft component of the GORE EXCLUDER Iliac Branch Endoprosthesis.
P020004/S134	07/11/2016	X - 30-Day Notice	GORE EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES, INC	Implementation of the manufacture of the 23mm and 27mm sizes of the GORE EXCLUDER AAA Endoprosthesis Contralateral Leg components at the Sunnyvale manufacturing facility.
P020004/S135	07/29/2016	X - 30-Day Notice	GORE EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES, INC	Implementation of a replicate manufacturing process for wrapped components of the GORE EXCLUDER AAA Endoprosthesis in Gore's Sunnyvale facility.
P020045/S076	07/07/2016	X - 30-Day Notice	FREEZOR FAMILY CARDIAC CRYOABLATION CATHETERS	MEDTRONIC CRYOCATH LP	Acceptance of new impedance criteria for the fluid detection circuit and modified related in-process and final inspection test equipment software.

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P030017/S253	07/28/2016	X - 30-Day Notice	PRECISION SPINAL CORD, SPECTRA, NOVI, MONTAGE MRI & PRECISION MONTAGE SPINAL CORD STIMULATION(SCS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Suppliers change in site of manufacture of the Stylet Cap Cover component used with Infinion CX Leads.
P030017/S254	07/29/2016	X - 30-Day Notice	PRECISION, SPECTRA, NOVI, SPINAL CORD STIMULATION(SCS) SYSTEM; PRECISION MONTAGE MRI AND MONTAGE SPINAL CORD STIMULATOR (SCS) SYSTEMS.	BOSTON SCIENTIFIC CORP.	Change in the manufacturing process to integrate two tests into one test system.
P030023/S005	07/06/2016	X - 30-Day Notice	RINGJECT	OPHTEC USA, INC.	Modification of the current blunt finish distal tip on capsular tension ring (CTR) injector to an angular (beveled) distal tip finish.
P030031/S075	07/18/2016	X - 30-Day Notice	THERMOCOOL SMARTTOUCH UNI-DIRECTIONAL NAVIGATION CATHETER	BIOSENSE WEBSTER, INC.	Use of new equipment, the Output Control System, to inspect connectivity of force and navigation sensor coils, the data on the device EEPROM, and compare EEPROM information as well as physical attributes against the Work Order Packet Requirements.
P030036/S085	07/14/2016	X - 30-Day Notice	SELECTSECURE LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of a peel strength test to the manufacturing process.
P030050/S024	07/07/2016	X - 30-Day Notice	SCULPTRA AND SCULPTRA AESTHETIC	Q-MED AB	Change to the sterility testing method.
P030053/S035	07/05/2016	X - 30-Day Notice	MENTOR MEMORYGEL BREAST IMPLANTS	MENTOR CORP.	Use of previously approved Semi-Automated Primary Packaging Equipment SPPS following relocation from the Main Assembly Controlled Manufacturing Environment CME room to the Primary Packaging CME Room at the Mentor Irving, Texas facility.
P030054/S305	07/19/2016	X - 30-Day Notice	QUICKFLEX U, QUARTET	St. Jude Medical	Alternate analytical testing laboratory for the identification testing of dexamethasone sodium phosphate for incoming monolithic controlled release devices.
P030054/S306	07/19/2016	X - 30-Day Notice	PROMOTE + ICDS	St. Jude Medical	Changes to the hybrid solder reflow process.

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P030054/S306	07/19/2016	X - 30-Day Notice	PROMOTE + ICDS	ST. JUDE MEDICAL	Changes to the hybrid solder reflow process.
P040021/S029	07/26/2016	X - 30-Day Notice	BIOCOR VALVE, SUPRA VALVE; EPIC VALVE, SUPRA VALVE; TRIFECTA VALVE, TRIFECTA VALVE WITH GLIDE TECHONOLGY (TRIFECTA GT)	ST. JUDE MEDICAL, INC.	Addition of three new bovine and porcine tissue suppliers.
P040036/S056	07/18/2016	X - 30-Day Notice	THERMOCOOL SMARTTOUCH BI-DIRECTIONAL NAVIGATION CATHETER	BIOSENSE WEBSTER, INC.	Use of new equipment, the Output Control System, to inspect connectivity of force and navigation sensor coils, the data on the device EEPROM, and compare EEPROM information as well as physical attributes against the Work Order Packet Requirements.
P040044/S073	07/06/2016	X - 30-Day Notice	MYNX ACE VASCULAR CLOSURE DEVICE	ACCESS CLOSURE, INC.	Add a second sterilization line at a previously approved alternate sterilization facility (Synergy Health in San Diego, California).
P050017/S013	07/01/2016	X - 30-Day Notice	ZILVER VASCULAR STENT	COOK INCORPORATED	Alternate resin for several delivery system components.
P050037/S075	07/29/2016	X - 30-Day Notice	RADIESSE 1.5CC	MERZ NORTH AMERICA, INC	Modification of the nozzle used in the semi-automated filling process to fill RADIESSE product syringes.
P050039/S019	07/21/2016	X - 30-Day Notice	NOVATION CERAMIC ARTICULATION HIP SYSTEM	EXACTECH, INC.	Addition of an extra sealer for the packaging process. The new equipment is intended for the sealing of packages for the acetabular liner and femoral head components and mating bone screw components used with the Exactech Novation Ceramic Articulation Hip System (AHS).
P050051/S031	07/13/2016	X - 30-Day Notice	ABBOTT ARCHITECT AUSAB	ABBOTT LABORATORIES INC	Relocation of manufacturing activities for the purification and production of antigens used in final test components.
P050052/S087	07/29/2016	X - 30-Day Notice	RADIESSE 0.8CC AND 1.5CC	MERZ NORTH AMERICA, INC	Modification of the nozzle used in the semi-automated filling process to fill RADIESSE product syringes.
P060006/S074	07/13/2016	X - 30-Day Notice	EXPRESS SD RENAL MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Process changes associated with etching, polishing, and cleaning the stent component.
P060028/S018	07/05/2016	X - 30-Day Notice	MENTOR MEMORYSHAPE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Use of previously approved Semi-Automated Primary Packaging Equipment SPPS following relocation from the Main Assembly Controlled Manufacturing Environment CME room to the Primary Packaging CME Room at the Mentor Irving, Texas facility.

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P060038/S028	07/14/2016	X - 30-Day Notice	MITROFLOW AORTIC PERICARDIAL HEART VALVE	LIVANOVA CANADA CORP.	Introduction of an alternative verification test method used to verify the Isopropyl Alcohol (IPA) concentration of the sterilant solution.
P060039/S070	07/07/2016	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Use of new instrumentation and an update to the analytical test method for monomer tubing.
P060039/S071	07/14/2016	X - 30-Day Notice	ATTAIN STARFIX MODEL 4195 LEAD	MEDTRONIC INC.	Implementation of a peel strength test to the manufacturing process.
P070026/S037	07/01/2016	X - 30-Day Notice	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Introduction of digital, automated hydrometers and water flow rate alarms for products of the CERAMAX® Ceramic Total Hip System that are processed through the final clean lines.
P080006/S096	07/14/2016	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD; ATTAIN PERFORMA LEAD	MEDTRONIC INC.	Implementation of a peel strength test to the manufacturing process.
P080020/S021	07/25/2016	X - 30-Day Notice	GEL-ONE	SEIKAGAKU CORP.	Update the application software for the existing intrinsic viscosity measuring system used for the manufacture of Gel-One.
P080025/S109	07/01/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM (BOWEL)	MEDTRONIC NEUROMODULATION	Relocate the manufacturing facility for an external supplier of components for neuromodulation leads.
P080025/S110	07/07/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Process parameter changes related to package sealing, tray cleaning, and packaging inspection.
P080025/S111	07/07/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM FOR BOWEL	MEDTRONIC NEUROMODULATION	Addition of new peel test and pouch seal equipment used in the Pouch Sealing process and Blister Package and Pouch Peel Testing process and introduction of a new peel test operation procedure at the Medtronic Sullivan Lake facility.
P080025/S112	07/13/2016	X - 30-Day Notice	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR BOWEL	MEDTRONIC NEUROMODULATION	Changes to tapering process for tubing used on leads from a manual tapering process to a semi-automated tapering process and replacement of a ring gauge outer diameter measurement system with a laser micrometer.
P080025/S114	07/27/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Update to the welding process parameters, welding electrode tip geometry, and accompanying documentation used in the manufacture of your Medium Rate battery assemblies for your Restore, Itrel, and Synergy Spinal Cord Stimulation (SCS) Systems; Activa Deep Brain Stimulation (DBS) Therapy System; Activa Dystonia Therapy System; Reclaim DBS Therapy for OCD System; InterStim Therapy System; Enterra Therapy System; and SyncroMed Infusion System.

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P080025/S115	07/20/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Implementation of peel strength testing in the manufacturing lines at Medtronic Puerto Rico Operations Co. Villalba and Medtronic Puerto Rico Operations Juncos.
P090003/S041	07/13/2016	X - 30-Day Notice	EXPRESS LD ILIAC OVER-THE-WIRE PREMOUNTED STENT SYSTEM	Boston Scientific Corporation	Process changes associated with etching, polishing, and cleaning the stent component.
P090013/S227	07/06/2016	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	New instrumentation and an updated test method for use in the battery manufacturing process.
P090013/S228	07/20/2016	X - 30-Day Notice	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Alternate printed wiring board for use in hybrid manufacturing.
P090013/S229	07/14/2016	X - 30-Day Notice	REVO MRI SURESCAN IPG AND CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Implementation of a peel strength test to the manufacturing process.
P100009/S020	07/05/2016	X - 30-Day Notice	MITRACLIP AND MITRACLIP NT CLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Expand the cleanroom at the Menlo Park, California facility.
P100010/S057	07/07/2016	X - 30-Day Notice	ARCTIC FRONT FAMILY CARDIAC CRYOABLATION CATHETERS	MEDTRONIC CRYOCATH LP	Acceptance of new impedance criteria for the fluid detection circuit and modified related in-process and final inspection test equipment software.
P100022/S018	07/01/2016	X - 30-Day Notice	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK MEDICAL INCORPORATED	Alternate resin for several delivery system components.
P100029/S022	07/26/2016	X - 30-Day Notice	BIOCOR VALVE, SUPRA VALVE; EPIC VALVE, SUPRA VALVE; TRIFECTA VALVE,	ST. JUDE MEDICAL, INC.	Addition of three new bovine and porcine tissue suppliers.
P100040/S026	07/29/2016	X - 30-Day Notice	VALIANT THORACIC STENT GRAFT WITH CAPTIVIA DELIVERY SYSTEM	MEDTRONIC VASCULAR	Stent graft edge trimming process change for the Valiant Thoracic Stent Graft.
P110012/S010	07/13/2016	X - 30-Day Notice	VYSIS ALK BREAK APART FISH PROBE KIT	ABBOTT MOLECULAR, INC.	Removal of testing at the cell pellet stage for 2 components of the PathVysion HER-2 DNA Probe Kit: (1) ProbeChek HER-2/neu Cut-Off Control Slides (List No. 02J04-030), (2) ProbeChek HER-2/neu Normal Control Slides (List No. 02J05-030). The second change involves adding the RM2255 Rotary Microtome to the manufacturing procedures of the ProbeChek HER-2/neu Cut-Off Control Slides, the ProbeChek Her-2/neu Normal Control Slides and 2 components of the Vysis ALK Break Apart FISH Probe Kit: (1) ProbeChek ALK Normal

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P110013/S072	07/06/2016	X - 30-Day Notice	RESOLUTE INTEGRITY ZOTAROLIMUS ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Option to use an Incubator Shaker apparatus for elution testing.
P110013/S073	07/21/2016	X - 30-Day Notice	RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Implementation of an alternate solvent in the stent pre-clean manufacturing process.
P120017/S004	07/14/2016	X - 30-Day Notice	MYOCARDIAL PACING LEAD	MEDTRONIC INC.	Implementation of a peel strength test to the manufacturing process.
P130009/S063	07/21/2016	X - 30-Day Notice	EDWARDS EXPANDABLE INTRODUCER SHEATH SET	EDWARDS LIFESCIENCE S, LLC.	Modifications to the UV curing manufacturing process for the eSheath.
P130017/S011	07/26/2016	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Qualification of a new water system.
P130028/S010	07/13/2016	X - 30-Day Notice	ALGOVITA SPINAL CORD STIMULATION SYSTEM	NUVECTRA CORPORATION	Acceptance of an alternate manufacturing site for the supplier of the Algovita IPG electrical connector components.
P140010/S020	07/08/2016	X - 30-Day Notice	IN PACT ADMIRAL PACLITAXEL-COATED PERCUTANEOUS	MEDTRONIC INC.	Changes to the manufacturing and inspection processes for the catheter body sub-assembly.
P140015/S009	07/08/2016	X - 30-Day Notice	T:SLIM G4 INSULIN PUMP WITH DEXCOM G4 PLATINUM CGM	TANDEM DIABETES CARE, INC.	Implement a pump refurbishment process for the t:slim G4 Insulin Pump. The refurbishment activities will be conducted in the same building where current pump manufacturing occurs, 11045 Roselle, San Diego, CA. The t:slim G4 Insulin Pump is a component of the t:slim G4 Insulin Pump with
P140015/S010	07/20/2016	X - 30-Day Notice	T:SLIM G4TM INSULIN PUMP WITH DEXCOM G4 PLATINUM CGM	TANDEM DIABETES CARE, INC.	Automate the software loading process performed during manufacture of the t:slim G4 Insulin Pump at the Tandem Diabetes Care manufacturing plant in San Diego, CA. The t:slim G4 Insulin Pump is a component of the Dexcom G4 Platinum CGM System. The proposed change does not alter the
P140018/S002	07/27/2016	X - 30-Day Notice	VENASEAL CLOSURE SYSTEM	MEDTRONIC VASCULAR INC	Implementation of an alternative test method for determination of Butylated hydroxyanisole (BHA) in the n-butyl cyanoacrylate (nBCA) monomer at incoming inspection as well as in the VenaSeal adhesive formulation.
P140026/S003	07/05/2016	X - 30-Day Notice	ENROUTE TRANSCAROTID STENT SYSTEM	SILK ROAD MEDICAL, INC	Supplier site change.

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P150012/S009	07/25/2016	X - 30-Day Notice	INGEVITY LEAD	BOSTONSCIENTIFIC	Change in a reactant used for preparation of the key intermediate in the synthesis of dexamethasone acetate.
P150012/S010	07/26/2016	X - 30-Day Notice	INGEVITY MRI LEAD, INGEVITY NON-MRI LEAD	BOSTONSCIENTIFIC	Modified welding fixture for use in the manufacturing of the Ingevity family of pacemaker leads.
P150016/S001	07/27/2016	X - 30-Day Notice	TRIDYNE VASCULAR SEALANT	NEOMEND, INC.	Expansion of the cleanrooms used in the manufacture of Tridyne Vascular Sealant at the existing location, 60 Technology Drive, Irvine, California.
P150033/S004	07/28/2016	X - 30-Day Notice	MICRA TRANSCATHETER PACING SYSTEM MC1VR01	MEDTRONIC INC.	Update to the distribution control sorter tool system.

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